UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,235	10/27/2003	N. Sandor Racz	2102-4389US	3743

24247 7590 08/19/2011

TRASKBRITT, P.C.
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
CAMPBELL, VICTORIA P	
ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
08/19/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/694,235	RACZ ET AL.	
	Examiner	Art Unit	
	VICTORIA P. CAMPBELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,12-23,25-32 and 34-38* is/are pending in the application.

4a) Of the above claim(s) *7,13,19,22 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,8,9,12,14-18,20,21,23,25,27-32 and 34-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/1/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the second Office Action following the second Request for Continued Examination based on the 10/694235 application filed October 27, 2003. Claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32, 34-38 as amended and newly presented in the response filed May 23, 2011 are currently pending and considered below.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,871,470 to McWha in view of USPN 5,250,035 to Smith et al.

Regarding claims 1-6, 8, 9, 12, 14, 15, 29, and 32, McWha teaches a flexible spinal needle catheter assembly (10) comprising: a flexible needle catheter (12), said flexible needle catheter defining a hollow bore (14) for conveying medicating agent therethrough, said bore extending through a length of said flexible needle catheter, said flexible needle catheter having a proximal end which defines a leading edge (16; Fig. 2); a support needle releasably secured to said flexible needle catheter (22), said support needle being disposed within said hollow bore of said flexible needle catheter (Fig. 2), said support needle having a first end which defines a pencil point, non-cutting piercing point (27) configured for penetrating the dura mater of a patient (46; Fig. 6), said support needle having an outside diameter sized so that upon withdrawal of the flexible spinal needle catheter assembly from a dura mater of a spine of a patient, subsequent to an insertion of said assembly through the dura mater, a puncture opening produced by said insertion is of dimensions which permit the dura mater substantially to reseal said puncture opening formerly occupied by the flexible spinal needle assembly within said dura mater (The examiner notes that the phrase beginning with "sized so that" has been interpreted as functional language and as such, the prior art need be only capable

of performing the function above, and based on the size chosen, McWha would have been capable of performing the above function.), said support needle defining a hollow lumen (24) which extends along a length of said support needle and an opening (29), defined proximate said first end, which communicates the environment with said lumen, said support needle being positionable (this term has been interpreted to mean "capable of being positioned" and as such the device of the prior art need only have the structure capable of performing the following function(s)) in two conditions relative to said flexible needle catheter; in a first condition said support needle being positioned with said first end being positioned outside of said bore of said flexible needle catheter, said non-cutting piercing point and said opening being positioned outside of said bore (Fig. 3), the opening being positioned contiguous to the leading edge of the flexible needle catheter (the examiner notes that the flexible needle catheter is extended from the position shown in Figure 2 to that shown in Figure 3 and as such, as the opening passes the leading edge, they are contiguous) and in a second condition said support needle being removed from within said hollow bore of said flexible needle catheter (Fig. 1 shows the components are separable and may be located apart from one another either before or after use), and a solid stylet (25), releasably secured within said lumen, said stylet being positioned in a first condition to preclude access from the environment to said lumen through said opening (Col. 5, lines 61-65). Furthermore, McWha teaches that said leading edge of said flexible needle catheter is positioned proximate said pencil point tip (Fig. 3), that the flexible needle assembly has a leading edge configured and arranged to provide a feedback signal to indicate dural puncture (Col. 2, lines 1-8),

that a rear end of said support needle carries a support hub (30) having a first attach structure (33); and a proximal end of said flexible needle carries a flexible needle hub (20) having a second attach structure (32) configured to removably attach to the first attach structure carried by said support hub (by rotation), that the first and second attach structures comprise a luer lock type connection (17; Fig. 2), and that the flexible needle hub is configured for substantially unobtrusive attachment to a patient's skin by way of an intermediary adhesive element (the examiner notes that the device of McWha is capable of being taped to a patient's skin). Additionally, McWha teaches that a rear end of said support needle carries a support hub (30); and a proximal end of said flexible needle carries a flexible needle hub (20) having a detach structure (32) configured to detach the flexible needle hub from the support hub (by rotation), that a proximal end of said flexible needle carries a flexible needle hub (20); and a rear end of said support needle carries a support hub (30) having a detach structure (33) configured to detach the flexible needle hub from the support hub, that said flexible needle comprises a force absorbing structure to prevent kinking when the flexible needle is overly flexed (outer hub sleeve, see Figure below), and that said force absorbing structure comprises a flexible kink sleeve disposed on a portion thereof (see Figure below). McWha further teaches that said stylet is slidably mounted in said support needle (Fig. 1), that said first end of said flexible needle catheter is tapered into a curve to blend smoothly into the outer surface of said support needle (Fig. 4A), and that said flexible needle catheter is disposed on an outer surface of said support needle (Fig. 2).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).

Regarding claims 16-18, 20, 21, 23, and 35, McWha teaches a flexible spinal needle assembly (10) for inserting a distal end of a flexible spinal needle through dura mater into a spine of a patient, said flexible spinal needle assembly comprising: a flexible needle (12) having a bore through a length thereof; a support needle (22) having a proximal end (20) and a pencil point non-cutting piercing point at a distal end (27), said support needle being releaseably secured to said flexible needle to resist relative motion between a distal end of said flexible needle and said pencil point non-cutting piercing point during insertion of said flexible spinal needle assembly into a patient (via threads 32, 33); wherein said flexible needle is carried exterior to said support needle to expose said non-cutting piercing point when said assembly is positioned for said inserting (Fig. 3), and wherein said support needle is positionable (this term has been interpreted to mean "capable of being positioned" and as such the prior art need only disclose a structure capable of meeting the claimed limitations) in two conditions relative to said flexible needle; in a first condition said support needle is positioned with said bore of said flexible needle with said distal of end of said support needle being positioned outside of said internal bore of said flexible needle, said non-cutting piercing

point and said opening being positioned outside of said bore (Fig. 3); and in a second condition said support needle being removed from within said bore of said flexible needle catheter (Fig. 1; see above note on claim 1). McWha further teaches that said flexible needle has an exterior diameter configured such that withdrawal of said flexible needle from said dura mater, subsequent to insertion of the flexible needle assembly therethrough, permits said dura mater substantially to reseal a space formerly occupied by said flexible needle, and a tip and a flexible needle body of said flexible needle are of substantial elongated extent to be further extendable into the dura mater upon extraction of said support needle (The examiner notes that the phrase beginning with "configured such that" has been interpreted as functional language and as such, the prior art need be only capable of performing the function above, and based on the size chosen, McWha would have been capable of performing the above function.), and that said proximal end of said support needle carries a support hub (30) having a first attach structure (33); a proximal end of said flexible needle carries a flexible needle hub (20) having a second attach structure (32) configured to interface in removable interference with said first attach structure carried by said support hub (via rotation). Furthermore, McWha teaches a distal end of said assembly being constructed to provide a perceptible feedback signal when said distal end of said flexible needle penetrates said dura mater (Col. 2, lines 1-8), that the flexible needle hub further being configured for attachment to medical fluid transfer equipment having structure to form a luer lock type connection (17), and that said flexible needle comprises a kink sleeve disposed on a portion thereof, said kink sleeve configured to prevent kinking of said flexible needle

when said flexible needle is extended beyond the substantial flexure point during use (outer hub sleeve; see Figure below).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).

Regarding claim 25, McWha teaches a flexible spinal needle (10) comprising: a support needle (22) having a pencil point, non-cutting piercing tip (27), said support needle defining an interior lumen and an opening (the lumen begins at opening 29), said opening communicating said interior lumen with the exterior of said support needle; a flexible needle body (12) comprising an elongated hollow tube, said flexible needle body configured to be removably (after use in the patient, the components are separable) and slidably mounted on an exterior of said support needle (Figs. 2 and 3); and a flexible kink sleeve (the examiner notes that all structures have some degree of flexibility and as such has considered the kink sleeve of McWha to be flexible) disposed on a portion of said flexible needle body, said flexible kink sleeve being configured to prevent kinking of said flexible needle body, when said flexible needle body is bent beyond a flexible structural resilience thereof during use (outer hub sleeve; see Figure below), and wherein said support needle is positionable (this term has been interpreted to mean "capable of being positioned" and as such the prior art need only disclose a structure

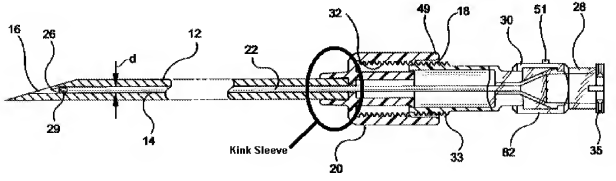
capable of meeting the claimed limitations) in two conditions relative to said flexible needle body; in a first condition said flexible needle body is mounted on said exterior of said support needle, said support needle being positioned with said first end of said support needle extending beyond said leading edge of said flexible needle body (Fig. 3); and in a second condition said support needle is removed from physical contact with said flexible needle body (Fig. 1; see above note on claim 1).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).

Regarding claim 27, McWha teaches a flexible spinal needle assembly (10) comprising: a support needle (22) comprising a first end defining a pencil point, non-cutting piercing point (27), and a hollow bore (24) with an opening (29) proximate said first end allowing access to said bore; and a flexible needle (12) slidably mounted on an exterior portion of said support needle (Figs. 2 and 3) such that said first end of said support needle protrudes from said flexible needle exposing said pencil point, non-cutting piercing point and said opening, wherein said flexible needle has sufficient transverse flexibility to accommodate patient torso bending movement so as to substantially reduce a patient's awareness of the presence of the flexible needle (Fig. 3), said flexible needle defining a lumen therein for transporting a medicinal agent;

wherein said support needle is positionable (this term has been interpreted to mean "capable of being positioned" and as such the prior art need only disclose a structure capable of meeting the claimed limitations) in two conditions relative to said flexible needle; in a first condition said support needle is positioned with said first end of said support needle extending beyond said leading edge of said flexible needle, said non-cutting piercing point and said opening being positioned beyond said leading edge (Fig. 3), the opening being contiguous to the leading edge (see note from claim 1); and in a second condition said support needle being removed from physical contact with said flexible needle (Fig. 1; see above note on claim 1).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon, a medical grade plastic) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).



12. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over McWha and Smith et al in view of USPGPub 2005/0070881 A1 to Gribbons et al.

McWha and Smith et al teach the limitations of claim 1 as taught above, but fail to teach or disclose a flat ribbon internal spring or metal band in the first end of the flexible needle catheter. Gribbons et al teach a flat metal ribbon or band (140) within the body of a catheter in order to provide support. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the flat metal band of Gribbons et al to the tip of the flexible needle catheter of McWha and Smith et al in order to further stabilize the tip to prevent bending during the insertion process.

5. Claims 34, 36, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over McWha and Smith et al as applied to claims 1, 16, 25, and 27 above, and further in view of USPGPub 2004/0236307 A1 to Klein.

McWha and Smith et al do not disclose that the plane containing the leading edge of the outer flexible needle is positioned perpendicularly to a longitudinal axis of the needle assembly. However, Klein teaches a cannula assembly having a flexible cannula and a stylet, wherein the stylet can be sharp-tipped (having a sloped leading edge) or blunt tipped (having a perpendicular leading edge) in the case that an incision already exists for insertion. At the time of invention, it would have been obvious to one having ordinary skill in the art to provide the device of McWha and Smith et al with a perpendicular or blunt leading edge on the flexible needle in order to follow a previous

channel or incision into the patient and prevent additional tissue damage from a sharp point veering off course.

Response to Arguments

6. Applicant's arguments filed May 23, 2011 have been fully considered but they are not persuasive.

7. Regarding applicant's argument that McWha does not disclose two conditions of the flexible and support needle, the examiner disagrees and notes that there is no frame of reference, order or other indication given as to where and when these spatial conditions must be met (ie: when inserted into the patient; or that the first state must occur before the second state; etc.) and as such the device of McWha is capable of many conditions of the flexible and support needles with respect to one another.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Friday, 7-3.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3763